VERMONT

# Vermont Health Access
# Pharmacy Benefit Management Program
# *DUR Board Meeting Minutes: 06/09/09*

**Board Members:**

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Norman Ward, M.D.
Lynne Vezina, R.Ph.
Stuart Graves, M.D.
Richard Harvie, R. Ph.

**Staff:**

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Nancy Hogue, Pharm.D. (MHP)
Nancy Miner, (MHP)
Stacey Baker, OVHA
Cynthia Laware, OVHA
Robin Farnsworth, OVHA
Jennifer Mullikin, OVHA
Judy Jamieson, OVHA
Esther Perelman, OVHA

**Guests:**

Steve Berardino, Amgen
Sherwanna Clarke, Abbott
John Coleman, Sanofi-Aventis
Michael Deorsey, Abbott
Pamela DiPerrio, GSK
Glenn E. Dooley, Sr, Sanofi-Aventis
Paul Fanikos, BIPI
Amy Finn, Merck
Mark Kaplan, Abbott
Terry Lalancette, GSK
Craig Lemley, Amylin
Thomas Leonard, GSK
Carl Marchand, AstraZeneca
Tim Nies, GSK
Moe Peguri, Abbott
Jiin Song, GSK
Jeffrey Steiger, GSK

Michael Scovner, M.D. Chair, called the meeting to order at 7:00 p.m. at the DUR Board meeting site in Williston.

## 1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

## 2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The May 2009 meeting minutes were accepted as printed.

*Public Comment*: No public comment.

## 3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Legislative Session: The Budget Bill is final and many of the changes will impact the pharmacy program. This includes requiring dispensing of maintenance medications in 90 day supplies, a 2 % reduction in reimbursement to pharmacies which will be obtained by an adjustment in reimbursement rates based on AWP, a reduction in out-of-state dispensing fees, changes in copayments in a variety of plans including VPharm, a generic/OTC pilot program in VPharm for the proton pump inhibitor and statin drug classes as well as seeking rebates in VPharm. Total savings are anticipated to be 6.5 million dollars in the pharmacy area.

**4. Medical Director Update:**

The position of Associate Medical Director (Erin Cody, M.D.) was eliminated with some of the budget cuts. There is an ongoing process to select a Medical Director in collaboration with the University of Vermont.

- Clinical Programs Update: The Chronic Care Initiative has been slightly cut back with the elimination of some positions.

- Prescriber Comments: No comments to report.

**5. Follow-up items from Previous Meeting:** *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Nplate® (romiplostim)
  Input regarding clinical criteria was obtained from two hematologists as requested by the DUR Board. It was recommended that coverage would require PA with the proposed revised criteria for approval being the patient is at least 18 years of age AND the diagnosis or indication is chronic immune (idiopathic) thrombocytopenic purpura (ITP) AND the patient's platelet count is less than 30,000/µL (< 30 x $10^9$/L) or the patient is actively bleeding AND the patient has had a documented side effect, allergy, treatment failure or a contraindication to therapy with corticosteroids OR the patient has a documented insufficient response following splenectomy. If Nplate® is approved, the proposed length of authorization is 3 months initially and 6 months upon recertification. Nplate® is only billable through the medical benefit. It is anticipated that consensus guidelines for treatment of ITP will be published sometime later this year.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the MHP recommendations noted above.

**6. Clinical Update: Drug Reviews:** *Diane Neal, R.Ph.( MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Cinryze® (C1 Inhibitor (human)) IV Infusion: It was recommended that coverage would require PA with the criteria for approval being the diagnosis or indication is **prophylaxis** of Hereditary Angioedema (HAE) attacks AND the patient has had a documented side effect, allergy, treatment failure or a contraindication to androgen therapy (i.e. danazol) AND the quantity requested does not exceed 16 vials per 28 days OR the medication is to be used for the **treatment** of an acute Hereditary Angioedema (HAE) attack AND the quantity requested per fill does not exceed 4 vials. If Cinryze® is approved, the proposed length of authorization is 6 months initially and 1 year upon recertification.

*Public Comment*: No public comment.

**Board Decision:** The Board unanimously approved the MHP recommendations noted above.

Promacta® (eltrombopag) Oral Tablet: It was recommended that coverage would require PA with the criteria for approval being the patient is at least 18 years of age AND the diagnosis or indication is chronic immune (idiopathic) thrombocytopenic purpura (ITP) AND the patient's platelet count is less than 30,000/µL (< 30 x $10^9$/L) or the patient is actively bleeding AND the patient has had a

documented side effect, allergy, treatment failure or a contraindication to therapy with corticosteroids OR the patient has a documented insufficient response following splenectomy. If Promacta® is approved, the proposed length of authorization is 3 months initially and 6 months upon recertification. It is anticipated that consensus guidelines for treatment of ITP will be published sometime later this year.

*Public Comment: Thomas Leonard, GSK* – Commented on the clinical efficacy, dosing and side effects of Promacta®.

**Board Decision:** The Board unanimously approved the MHP recommendations noted above.

- Trilipix® (fenofibric acid) Delayed Release Capsule: Recommended for addition to the PDL as preferred if on a statin concurrently or after a gemfibrozil trial. A quantity limit of one capsule per day was recommended. A revised Lipotropic: Fibric Acid Derivative clinical criteria manual table was presented and it was recommended that the duration of PA be changed to one year.

*Public Comment: Sherwanna Clarke, Abbott* – Discussed the clinical trials with Trilipix®, the lack of first pass metabolism and the lack of reported rhabdomyolysis cases.

**Board Decision:** The Board unanimously approved the MHP recommendations noted above including the revised clinical criteria manual page.

**7. Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- Medicare Part D Wrap Benefit – Statin/PPI drug classes:
The statins and proton pump inhibitor classes are the two most expensive drug classes in the VPharm program with the state paying in many cases for large branded product co-pays. This initiative requires the prescribing of certain generic/OTC statins and PPIs in order for the state to pay the cost sharing amount. These two drug classes were chosen as there are significantly less costly generic and OTC drug choices available that have been proven to be equally efficacious and well tolerated compared to the more expensive branded products. These drug classes also account for a significant amount of dollars spent in providing the VPharm wrap program. Additionally, approximately 50 % of prescriptions for patients in this program are already being written for preferred products and will not need to be changed. The covered generic statins are all strengths of simvastatin, lovastatin and pravastatin. In the PPI category, the covered products are omeprazole 10 and 20 mg and Prilosec OTC®. There will be a prior authorization process for prescribers with patients who can not be clinically treated with the preferred products.

*Public Comment:* No public comment.

**Board Decision:** The Board approved the list of covered generic/OTC PPIs and statins in the VPharm program as presented.

- Renal Disease: Phosphate Binders (sevelamer - Renvela®/Renagel®):
Originally, Genzyme had announced that Renagel® was not going to be manufactured after September 30, 2009. That decision has since been reversed and there are no immediate plans for its discontinuation. Consequently there was no need to discuss this category. The discussion will be deferred until a later date.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Required 90 Day Supply Maintenance Medications @ Retail – Drug Classes:
  The proposed list of maintenance medications categories where mandatory 90 day supplies are required was presented. Mental health medications have not been included. The proposed cost savings from reduced dispensing fees is 1.3 million dollars. The list was developed from the MediSpan maintenance medication list. One initial fill of 30 days will be allowed before a 90 day fill is required. The DUR Board expressed concern over waste and would like to figure out how that could be measured. Very expensive medications were not included in the list.

*Public Comment: Sherwanna Clarke, Abbott* - Asked whether utilization had been examined to look for ongoing continuation of therapy.

**Board Decision:** The Board approved the list of maintenance medication categories as presented with the request that insulin be removed from the list. The list of drug categories will be posted on the web and communicated to pharmacies and prescribers.

**8. Drug Classes – Annual Review:**
(Public comment prior to Board action)

**Pulmonary Agents**

- Anticholinergics (Antimuscarinics) **and** Beta-Agonist/Anticholinergic Combinations: No changes were recommended to the current approval criteria. Quantity limits were recommended for Atrovent HFA®, Spiriva® and Combivent®.

*Public Comment:* No public comment.

**Board Decision:** The Board approved leaving the current approval criteria and preferred drugs unchanged and accepted the proposed quantity limits.

- Antihistamines: Intranasal: No changes recommended.

*Public Comment:* No public comment.

**Board Decision:** The Board approved leaving the current approval criteria unchanged.

- Beta-Agonists: Single Agent: No changes were recommended to the current approval criteria. Quantity limits were recommended for Serevent Discus® and Foradil®.

*Public Comment:* No public comment.

**Board Decision:** The Board approved leaving the current approval criteria and preferred drugs unchanged and accepted the proposed quantity limits.

- Inhaled Glucocorticoids **and** Inhaled Glucocorticoid/Long Acting Beta-Agonist Combinations: No changes were recommended to the current approval criteria. Quantity limits were recommended for Flovent Diskus®, Advair Diskus® and Advair HFA®.

*Public Comment:* No public comment.

**Board Decision:** The Board approved leaving the current approval criteria and preferred drugs unchanged and accepted the proposed quantity limits.

- Nasal Glucocorticoids: No changes were recommended, however, the table will be updated to reflect that brand name Nasarel® is no longer available.

*Public Comment:* *Jiin Song, GSK* – Commented on the clinical benefits of Veramyst®.
*John Coleman, Sanofi Aventis* – Commented on the approval of Nasacort AQ® for use in children as young as two years old and the proven lack of growth suppression with its use.

**Board Decision:** The Board approved leaving the current approval criteria and preferred drugs unchanged.

- Leukotriene Modifiers: No changes were recommended to the current approval criteria. Quantity limits were recommended for Accolate®, Singulair® and Zyflo CR®. The table has been updated to reflect that regular release Zyflo® is no longer available.

*Public Comment:* No public comment.

**Board Decision:** The Board approved leaving the current approval criteria and preferred drugs unchanged and accepted the proposed quantity limits and accepted the revised table.

**9. RetroDUR:** *Diane Neal, R.Ph, (MHP)*

- No RetroDUR this month

**10. New Drug Product Plan Exclusions (Consent Agenda Topic):** *Diane Neal, R.Ph, (MHP)*

- Deferred until September meeting.

**11. Updated New-to-Market Monitoring Log (Consent Agenda Topic):** *Diane Neal, R.Ph, (MHP)*

- The log is posted on the web site as well as sent to the DUR Board members on their packet CD. This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

**12. General Announcements:** *Diane Neal, R.Ph, (MHP)*
**FDA Safety Alerts**

- No reports to discuss this month

**13. Adjourn:** Meeting adjourned at 8:38 p.m.

**Next DUR Board Meeting**
Tuesday, September 08, 2009
7:00 - 9:00 p.m.*

EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.